HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-13: Guidance on the Risk Classification of General Medical Devices

Revision 2.1

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REVISION HISTORY

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**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

1. INTRODUCTION

1.1. Purpose

This document provides guidance to assist product owners to classify medical devices using the appropriate risk-based classification rules.

1.2. Background

Regulatory controls should be proportional to the level of risk associated with a medical device. The level of regulatory control should increase with increasing degree of risk, taking account of the benefits offered by use of the device. Therefore, there is a need to classify medical devices based on their risks to patients, users and other persons.

The risk presented by a particular medical device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

The risk presented by a medical device also depends, in part, on its intended user(s), its mode of operation, and/or technologies. In general, the risk classification rules are intended to accommodate new technologies.

1.3. Scope

This document is applicable to all device products that fall within the definition of a medical device found in the First Schedule of the Health Products Act (*Act*), other than those used for *in vitro* examination of specimens derived from the human body.

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1.4. Definitions

Definitions that do not indicate they are set out in the *Act* and Health Products (Medical Devices) Regulations 2010 (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

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ACCESSORY: for the purposes of this guidance document, means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose. An accessory is typically intended to be used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device.

ACTIVE IMPLANTABLE MEDICAL DEVICE *(as set out in the Regulations)*: means any active medical device that is intended by its product owner to be introduced, either by surgical or medical intervention, wholly or partially into the body of a human being; or by medical intervention, into a body orifice; and, to remain in place after the procedure.

ACTIVE MEDICAL DEVICE *(as set out in the Regulations)*: means any medical device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy, but does not include any medical device intended to transmit energy, substances or other element between that medical device and a patient without any significant change to that energy, substance or element.

NOTE Standalone software is deemed to be an active medical device.

NOTE The concept "act by converting energy" includes conversion of energy from the power source to another form of energy. For example, from electrical source to thermal energy.

The application of energy from the human body does not make a device "active" unless that energy is stored within the device for subsequent release. For instance, energy generated by human body and applied to the plunger of a syringe (thus causing a substance to be delivered to a patient) does not make this syringe an "active device". However, if a delivery system depends upon manual winding to preload a spring which is subsequently released to deliver a substance, then the device incorporating the spring is an "active device".

Medical devices using prestored gases and/or vacuum as a power source are regarded as active devices, e.g. a pressurised canister delivery system.

Heating/cooling pads intended only to release stored thermal energy are not active devices because they do not act by conversion of energy. However, heating/cooling pads which act by chemical action (e.g. endothermic or exothermic reaction) are active devices as they are converting chemical energy into heat energy and or vice versa.

Radioactive sources that are intended to deliver ionising radiation are regarded as active medical devices (e.g. radioactive isotopes coated beads), unless they are radiopharmaceuticals which may be infused into the body.

ACTIVE THERAPEUTIC MEDICAL DEVICE *(as set out in the Regulations)*: means an active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap.

ACTIVE DIAGNOSTIC MEDICAL DEVICE *(as set out in the Regulations)*: means an active medical device used, whether alone or in combination with any other medical device, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity

BODY ORIFICE *(as set out in the Regulations)*: means any natural opening in a human body, the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

CENTRAL CIRCULATORY SYSTEM: For the purpose of this document, means the major internal blood vessels including the following:

- aorta abdominalis (abdominal aorta);
- aorta ascendens (ascending aorta);
- aorta descendens to the bifurcatio aortae (descending aorta to the bifurcation of aorta).
- aorta thoracica (thoracic aorta);
- arcus aorta (aortic arch);
- arteria carotis communis (common carotid artery);
- arteria carotis externa (external carotid artery);
- arteria carotis interna (internal carotid artery);
- arteriae cerebrates (cerebella arteries);
- arteriae coronariae (coronary arteries);
- arteriae pulmonales (pulmonary arteries);
- ilica communis (common iliac arteries and veins);
- truncus brachicephalicus (brachiocephalic trunk);
- venae cava inferior (inferior vena cava);
- venae cava superior (superior vena cava);
- venae cordis (cardiac veins);
- venae pulmonales (pulmonary vein);

CENTRAL NERVOUS SYSTEM: means the brain, meninges and spinal cord.

DERIVATIVE: A 'non-cellular substance' extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.

DURATION OF USE

- TRANSIENT USE *(as set out in the Regulations)*: in relation to a medical device, means continuous use of the medical device for a period not exceeding 60 minutes.

- SHORT-TERM USE *(as set out in the Regulations)*: in relation to a medical device, means continuous use of the medical device for a period 60 minutes and 30 days.
- LONG-TERM USE *(as set out in the Regulations)*: in relation to a medical device, means continuous use of the medical device for a period exceeding 30 days.

NOTE For the purpose of this document, continuous use means:

- *the uninterrupted use of the medical device, not including any temporary interruption of its use during a procedure or any temporary removal of the medical device for purposes such as cleaning or disinfection; or*
- *the accumulated use of the medical device by replacing it immediately with another medical device of the same type, as intended by its product owner.*

HARM *(as set out in the Regulations)*: means any physical injury or damage to the health of a person, or any damage to property or the environment.

HAZARD *(as set out in the Regulations)*: means any potential source of harm.

IMMEDIATE DANGER: means a situation where a patient is at risk of losing his life or an important bodily function if no immediate preventative measure is taken.

IMPLANTABLE MEDICAL DEVICE *(as set out in the Regulations)*: means any medical device which is intended by its product owner:

- to be wholly introduced into a human body, or to replace a human epithelial surface or the surface of a human eye, by surgical intervention, and to remain in place after the surgical intervention; or
- to be partially introduced into a human body by surgical intervention, and to remain in place for at least 30 days after the surgical intervention,

and includes any such medical device that is wholly or partially absorbed by the human body, epithelial surface or eye.

INTENDED PURPOSE/INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

INVASIVE (BODY ORIFICE) MEDICAL DEVICE: means an invasive medical device, not being a surgically invasive medical device, which penetrates into a human body through a body orifice.

INVASIVE MEDICAL DEVICE *(as set out in the Regulations)*: means a medical device which, in whole or in part, penetrates inside a human body, either through a body orifice or through the surface of the body.

LIFE SUPPORTING OR LIFE SUSTAINING: in relation to a medical device, means that the medical device is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act.*

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

NON-INVASIVE MEDICAL DEVICE *(as set out in the Regulations)*: means a medical device other than an invasive medical device.

NON-VIABLE *(as set out in the Regulations)*: in relation to a biological entity, means that the entity is incapable of growth, development and reproduction.

PRIMARY INTENTION: in relation to the healing of a wound, means the manner of healing where the wound edges directly touch each other with minimal granulation tissue being formed.

REUSABLE SURGICAL INSTRUMENT: means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device, and which is intended to be reused after appropriate procedures for cleaning or sterilisation of the instrument have been carried out.

RISK *(as set out in the Regulations)*: means a combination of the probability of occurrence of harm and the severity of that harm.

STERILE STATE *(as set out in the Regulations)*: in relation to a medical device, means a state free of viable micro-organisms.

SURGICALLY INVASIVE MEDICAL DEVICE *(as set out in the Regulations)*: means an invasive medical device which penetrates into the body:

(a) through the surface of the body, with the aid or in the context of a surgical operation; or

(b) other than through a body orifice.

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2. FACTORS INFLUENCING MEDICAL DEVICE RISK CLASSIFICATION

A number of factors, including for example the duration of medical device contact with the body, the degree of invasiveness, whether the medical device delivers medicinal products or energy to the patient, whether they are intended to have a biological effect on the patient and local *versus* systemic effects (e.g. conventional *versus* absorbable sutures) may, alone or in combination, affect medical device risk classification.

If, based on the product owner's intended purpose, two or more risk classification rules apply to the medical device, the medical device is assigned the highest risk class.

Where one medical device is intended to be used together with another medical device, that may or may not be from the same product owner, (e.g. a physiological monitor and a separate recorder, or a general purpose syringe and a syringe driver), the risk classification rules shall apply separately to each of the medical devices.

Risk classification of an assemblage of medical devices that individually comply with all regulatory requirements depends on the product owner's purpose in packaging and marketing such a combination of separate medical devices. For example,

- if the combination results in a product that is intended by the product owner to meet a purpose different from that of the individual medical devices that make it up, the combination is a new medical device in its own right and should be classified according to the new intended purpose, or
- if the combination is for the convenience of the user but does not change the intended purposes of the individual medical devices that make it up (e.g. a customised kit that provides all the medical devices necessary to carry out a particular surgical procedure), the risk classification assigned to

the assemblage for the purpose of a Declaration of Conformity should be the same as that of the medical device with the highest risk class included within it.

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Accessories intended specifically by product owners to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose, shall be subjected to the regulatory requirements that apply to the medical device itself (e.g. essential principles for safety and performance, post-market surveillance, etc). An accessory is typically intended to be used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device. ◄

Most software is incorporated into the medical device itself, for example embedded software to operate an electrocardiogram. Some software applications are not incorporated (embedded) into the medical device itself, such as software applications to analyse electrocardiogram signals on a computer independent of the electrocardiogram. These are deemed to be standalone software. Such standalone software applications that fall within the scope of the definition for a 'medical device' should be classified as follows:

- where it drives or influences the use of a separate medical device, it should be classified according to the intended purpose of the combination.
- where it is independent of any other medical device, it is classified in its own right using the rules.
- standalone software is deemed to be an active medical device.

3. GENERAL RISK CLASSIFICATION SYSTEM FOR MEDICAL DEVICES

Table 1 indicates the four risk classes of medical devices. The examples given are for illustration only and the product owner must apply the risk classification rules to each medical device according to its intended purpose.

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Table 1: General risk classification system for medical devices

RISK CLASS	RISK LEVEL	MEDICAL DEVICE EXAMPLES
A	Low Risk	Wheelchairs / Tongue depressors
B	Low-moderate Risk	Hypodermic needles / Suction equipment
C	Moderate-high Risk	Ventilators / Bone fixation plates
D	High Risk	Heart valves / Implantable defibrillator

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4. THE DETERMINATION OF MEDICAL DEVICE RISK CLASS USING THE RULES-BASED SYSTEM

The product owner should:

- decide if the product concerned is a medical device, using the appropriate definition;
- document the intended purpose of the medical device; and
- take into consideration **ALL** the rules that follow in order to establish the proper risk classification for the device, noting that where a medical device has features that place it into more than one risk class, risk classification should be based on the **HIGHEST** risk class applicable.

NOTE Medical devices that are used for the in vitro examination of specimens derived from the human body are not covered by the risk classification rules within this document.

5. RISK CLASSIFICATION RULES

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The risk classification of each medical device depends on the design and claims made by the product owner and on its intended purpose. While the provision of illustrative notes and examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasised that the actual risk classification of a particular medical device must be considered individually, taking into account its design and intended purpose. ◄

RULE	NOTES FOR CONSIDERATION AND ILLUSTRATIVE EXAMPLES OF DEVICES THAT MAY CONFORM WITH A RULE
NON-INVASIVE DEVICES	
Rule 1. All non-invasive devices which come into contact with injured skin:	
- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, R2 ► for wounds that heal by primary intention. ◄	Examples: compression bandages; cotton wool.
- are in Class B if they are intended to be used R2 ► to manage the microenvironment of the wound. ◄	Examples: non-medicated impregnated gauze dressings.
Unless they are intended to be used principally with wounds R2 ► that cannot heal by primary intent, ◄ in which case they are in Class C.	Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be

	formed within the wound prior to external closure. The product owner claims that they promote healing through physical methods other than 'primary intent'. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.
R2 ► **Rule 2(i).** All non-invasive devices intended for • channelling tissues, • channelling or storing body liquids, liquids or gases for the purpose of eventual infusion, administration or introduction into a human body are in Class A, ◄	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body (see comment for Rule 4). Examples: administration sets for gravity infusion; syringes without needles.
Unless they are intended to be connected to an active medical device in Class B or a higher class, in which case they are in Class B;	Examples: syringes and administration sets for infusion pumps; anaesthesia breathing circuits. *NOTE: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-invasive device and vice versa.*
R2 ► **Rule 2(ii).** All non-invasive devices intended for they are intended for • channeling blood or blood components, or • -- • storing organs, parts of organs or body tissues,	Examples: tubes used for blood transfusion, organ storage containers, tissue and cell containers.

for the purpose of eventual infusion, administration or introduction into a human body are in Class B, ◄	
Unless they are blood bags, in which case they are in Class C.	Examples: blood bags, blood component storage bags.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of • blood, • other body liquids, or • other liquids intended for infusion into the body are in Class C,	Such devices are indirectly invasive in that they treat or modify substances that will eventually be delivered into the body (see note to comment for Rule 4). They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodialysers; devices to remove white blood cells from whole blood. *NOTE: For the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.*
Unless R2 ► the intended modification is carried out by ◄ filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.
Rule 4. All other non-invasive devices R2 ► that do not come into contact with the patient or contact intact skin only ◄ are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
INVASIVE DEVICES	
Rule 5. All invasive devices	Such devices are invasive in body orifices

with respect to body orifices (other than those which are surgically invasive) and which: • are not intended to be connected to an active medical device, or • are intended to be connected to a Class A medical device only.	and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
R2 ► **Unless** they are intended for transient use on the external surface of the eyeball, and are liable to be absorbed by the mucous membrane, in which case they are in Class B, ◄	Examples: wetting or lubricating eye drops.
- are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
Unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum, or in a nasal cavity, R2 ► and are not liable to be absorbed by the mucous membrane ◄ in which case they are in Class A,	Examples: dentures intended to be removed by the patient; dressings for nose bleeds.
- are in Class C if they are intended for long-term use;	Example: urethral stent.
Unless they are intended for	Examples: orthodontic wire, fixed dental

long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum, or in a nasal cavity, and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage. *NOTE: Independent of the time for which they are invasive.*
Rule 6. All surgically invasive devices intended for transient use are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker, etc. *NOTE: A surgical instrument (other than those in Class D) is in Class A if reusable and in Class B if supplied sterile and intended for single use. Also, a surgical instrument connected to an active device is in a higher class than A.* *NOTE: If the device incorporates a medicinal substance in a secondary role refer to Rule 13.*
Unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws.
Unless intended to supply energy in the form of ionising	Example: catheter incorporating/containing sealed radioisotopes.

radiation, in which case they are in Class C; or	
Unless intended to have a biological effect or R2 ► to be wholly or mainly absorbed by the human body, ◄ in which case they are in Class C; or	*NOTE: The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.* *NOTE: This part of the rule does not apply to those substances that are excreted without modification from the body.*
Unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking into account the mode of appli-cation, in which they are in Class C; or	Example: insulin pen for self-administration. *NOTE: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.*
Unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	
Unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of

	various types. Examples: infusion cannulae; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. *NOTE: Includes devices that are used during cardiac surgery but do not monitor or correct a defect.* *NOTE: If the device incorporates a medicinal substance in a secondary role refer to Rule 13.*
Unless they are intended to administer medicinal products, in which case they are in Class C; or	*NOTE: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling.*
Unless they are intended to undergo chemical change in the body (except if the devices are placed into the teeth), in which case they are in Class C; or	Example: surgical adhesive.
Unless they are intended to supply energy in the form or ionising radiation, in which case they are in Class C; or	Example: brachytherapy device.
Unless they are intended to have a biological effect or to be wholly or mainly absorbed by the human body, in which case they are in Class D; or	Example: absorbable suture; biological adhesive. *NOTE: The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.*
Unless they are intended specifically for use in direct contact with the central	Example: neurological catheter.

nervous system, in which case they are in Class D;	
Unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields. Example: maxilla-facial implants; prosthetic joint replacements; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating). *NOTE: If the device incorporates a medicinal substance in a secondary role refer to Rule 13.*
Unless they are intended to be placed into the teeth, in which case they are in Class B; or	Examples: bridges; crowns; dental filling materials.
Unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; spinal and vascular stents.
Unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	

Unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers, their electrodes and their leads; implantable defibrillators.
Unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive.
Unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: rechargeable non-active drug delivery system.
Unless they are intended to undergo chemical change in the body (except if the devices are placed into the teeth), in which case they are in Class D; or	
Unless they are breast implants, in which case they are in Class D.	
ACTIVE DEVICES	
Rule 9(i). All active therapeutic devices: • that are intended to administer or exchange energy R2 ► to or with the human body ◄, or • that are software, are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators. Examples: muscle stimulators; transcutaneous Electro-Neuro Stimulator (TENS) devices; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy, software and

	mobile application intended to treat diseases or conditions.
Unless their characteristics are such that they R2.1 ► function ◄ in a potentially hazardous way, including ionising radiation, taking into account the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionising radiation. *NOTE: The term 'potentially hazardous' refers to the type of technology involved and the intended application.*
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C R2 ► or higher, ◄ or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals, interventional radiology and diagnostic radiology.
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
- if they are intended to image *in vivo* distribution of	Example: gamma/nuclear cameras.

radiopharmaceuticals, or	
- if they are intended to allow direct diagnosis, or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs. *NOTE: Vital physiological processes and parameters include, for example respiration, cerebral functions, blood gases, blood pressure, body temperature, etc.*
Unless they are specifically intended for: • monitoring of vital physio-logical parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or • diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures. *NOTE: Medical devices intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care are in Class C, whilst medical devices intended to be used to obtain readings of vital physiological signals in routine check-ups and in self-monitoring are in Class B.*
Rule 10(ii). Active devices intended to emit ionising radiation and intended for	Example: these include devices for the control, monitoring or influencing of the emission of ionising radiation.

diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
Unless this is done in a manner that is potentially hazardous, taking into account the nature of the substances involved, the part of the body concerned and the mode and route of administration R2 ► or removal, ◄ in which case they are in Class C.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.

ADDITIONAL RULES	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, R2 ► is a registrable therapeutic/medicinal ◄ product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; drug eluting stents; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound. *NOTE: "Integral part" means that the device and the therapeutic/medicinal substance are physically or chemically combined at the time of administration (i.e. use, implantation, application, etc) to the patient.* *NOTE: This rule does not apply to products that incorporate therapeutic/medicinal substances that are not intended to act on the human body e.g. catheter surface modification or coating with silver or heparin substances that is solely intended to protect the catheter.*
Rule 14. All devices manufactured from or incorporating R2 ► • cells, tissues or derivatives of cells or tissues of animal origin, rendered non-viable, or • derivatives of cells or tissues of human origin, rendered non-viable, or • cells, tissues or derivatives of cells or tissues ◄ of recombinant origin	Examples: porcine heart valves; catgut sutures.

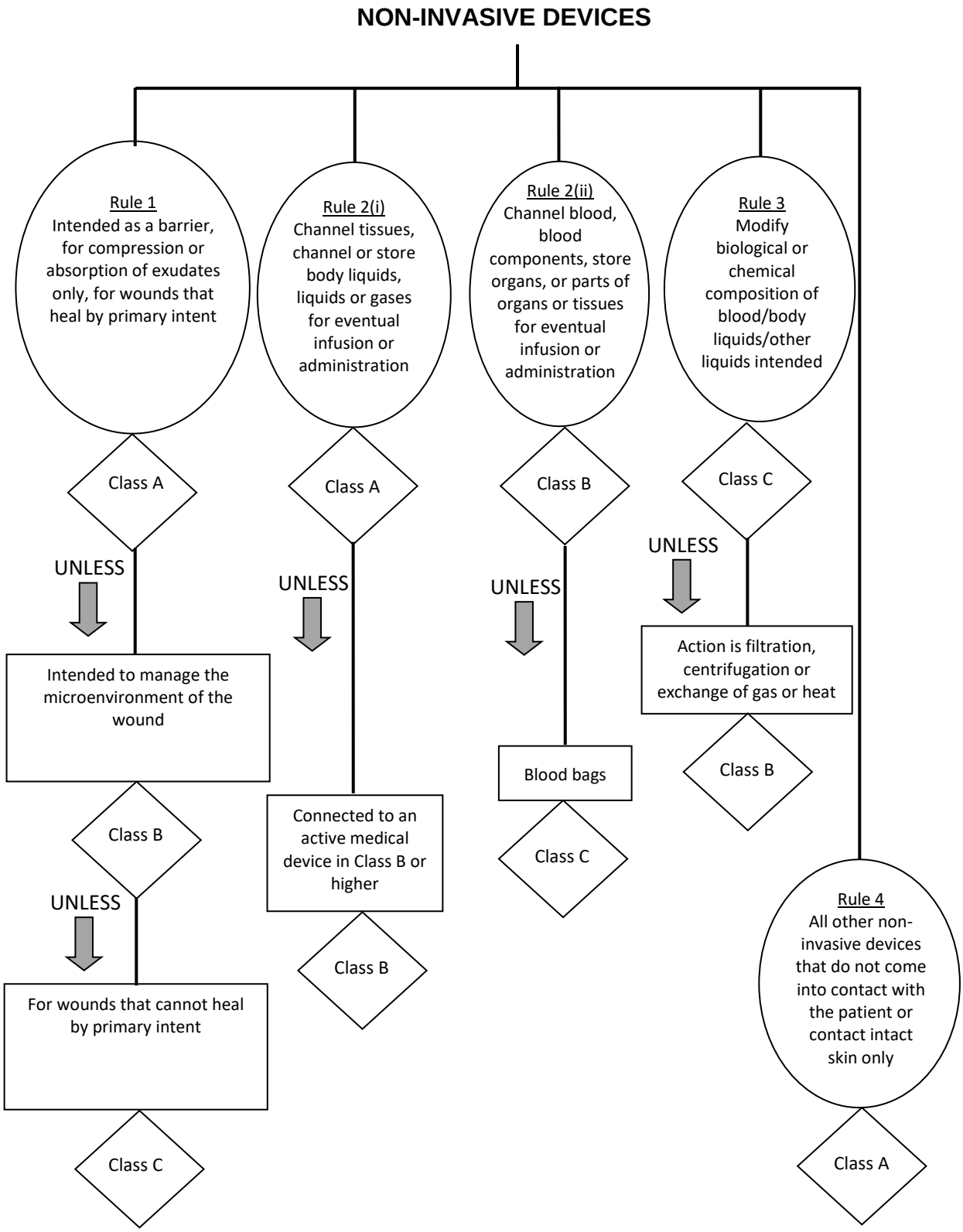
are Class D,	
Unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only, where they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilising medical devices, or disinfecting as the end point of processing, are in Class C.	Examples: devices for disinfecting or sterilising endoscopes; disinfectants intended to be used with medical devices. *NOTE: This rule does not apply to products that are intended to clean medical devices by means of physical action e.g. washing machines.*
Unless they are intended for disinfecting medical devices prior to end point sterilisation or higher level disinfection, in which case they are in Class B; or	Example: washer disinfectors.
Unless they are intended specifically to be used for disinfecting R2 ► -- ◄ or hydrating contact lenses, in which case they are in Class C.	
Rule 16. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
Unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

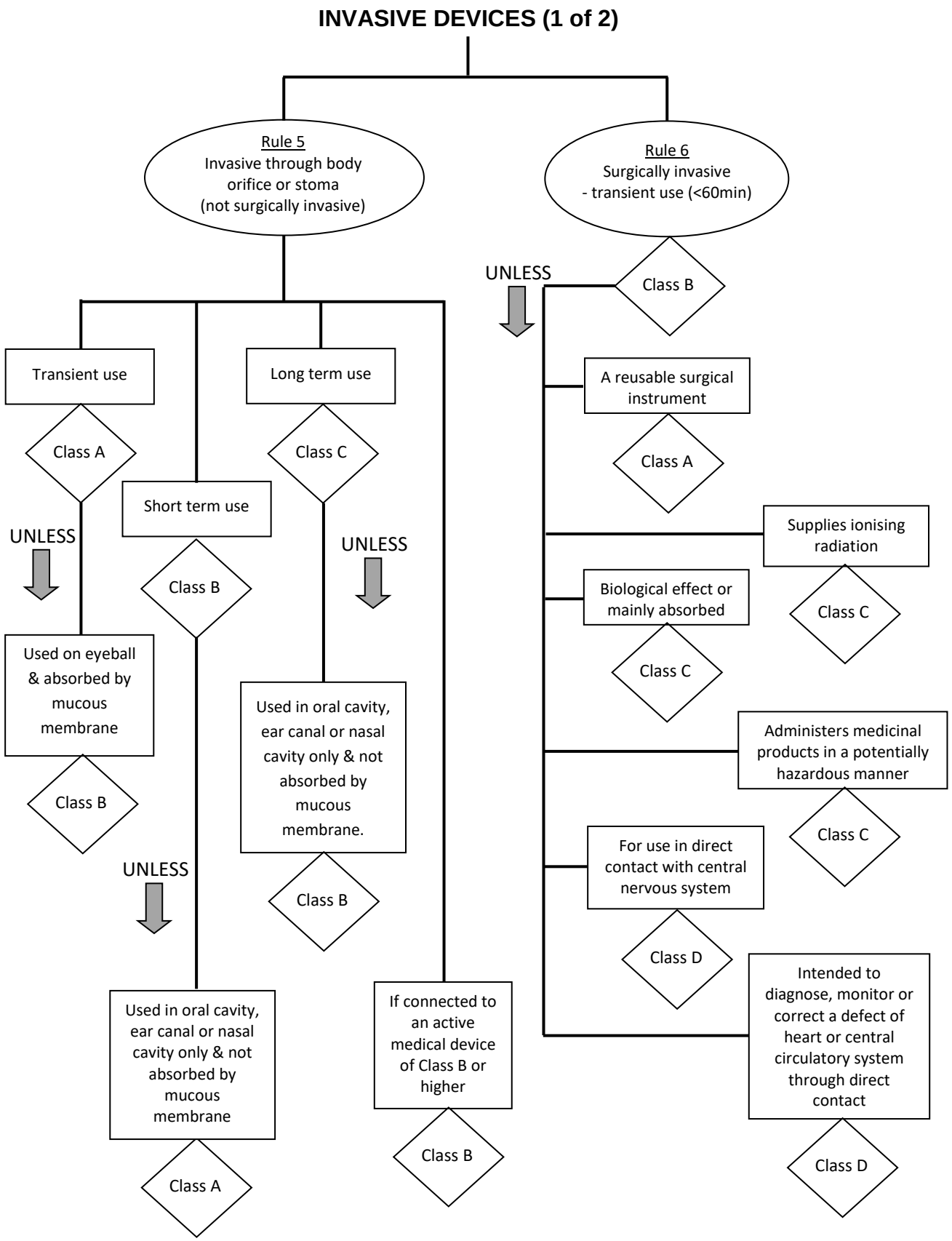
Decision trees illustrating how these rules may be used to classify specific medical devices are shown in **Appendix A**.

APPENDIX A

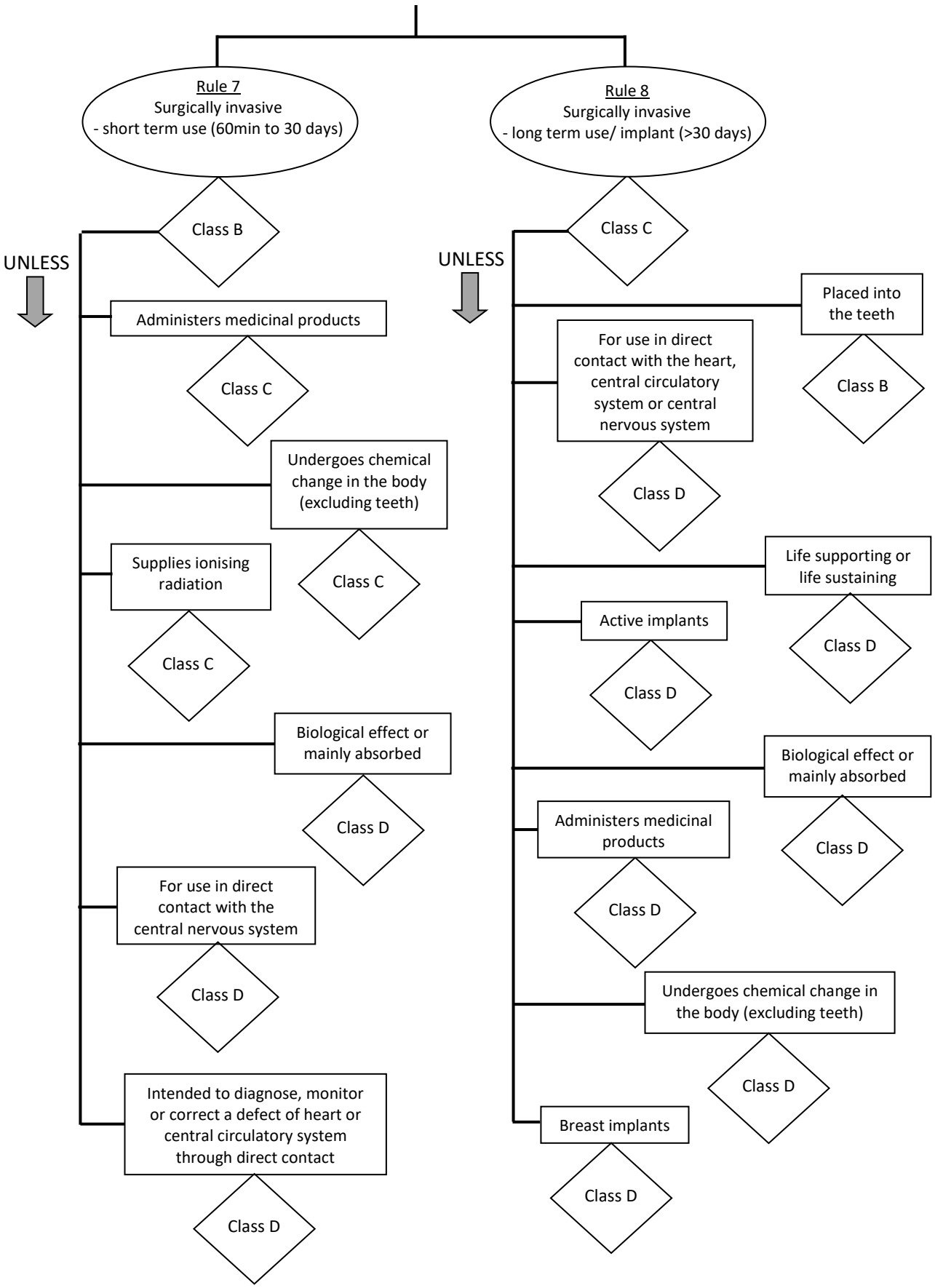
R2 ►

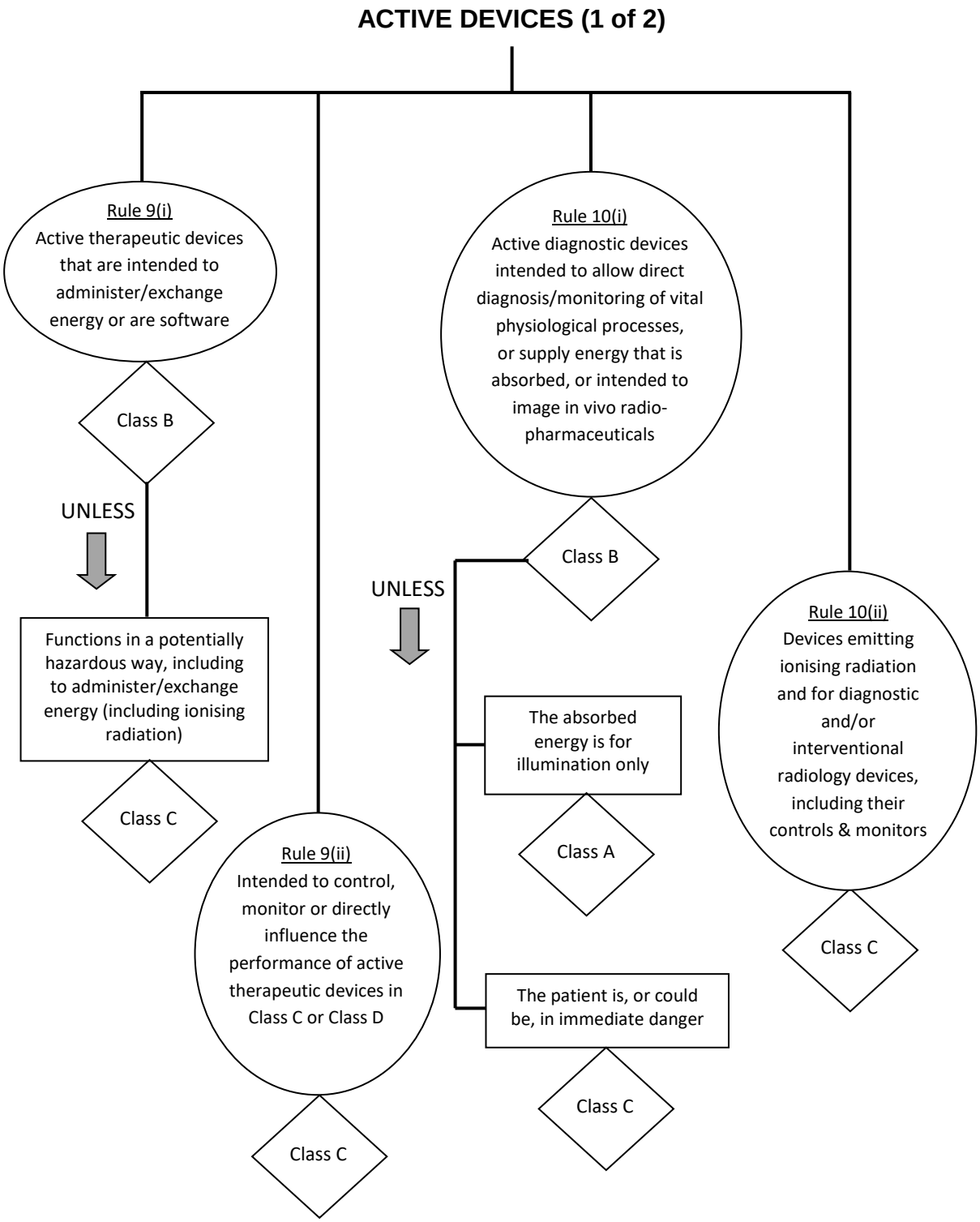
The diagrams that follow are for **illustrative purposes only** and the determination of risk class for a particular medical device should be made through reference to the rules and **not solely through the decision trees**. Where a medical device has characteristics that place it into more than one risk class, the final risk classification should be based on the **highest** risk class indicated.

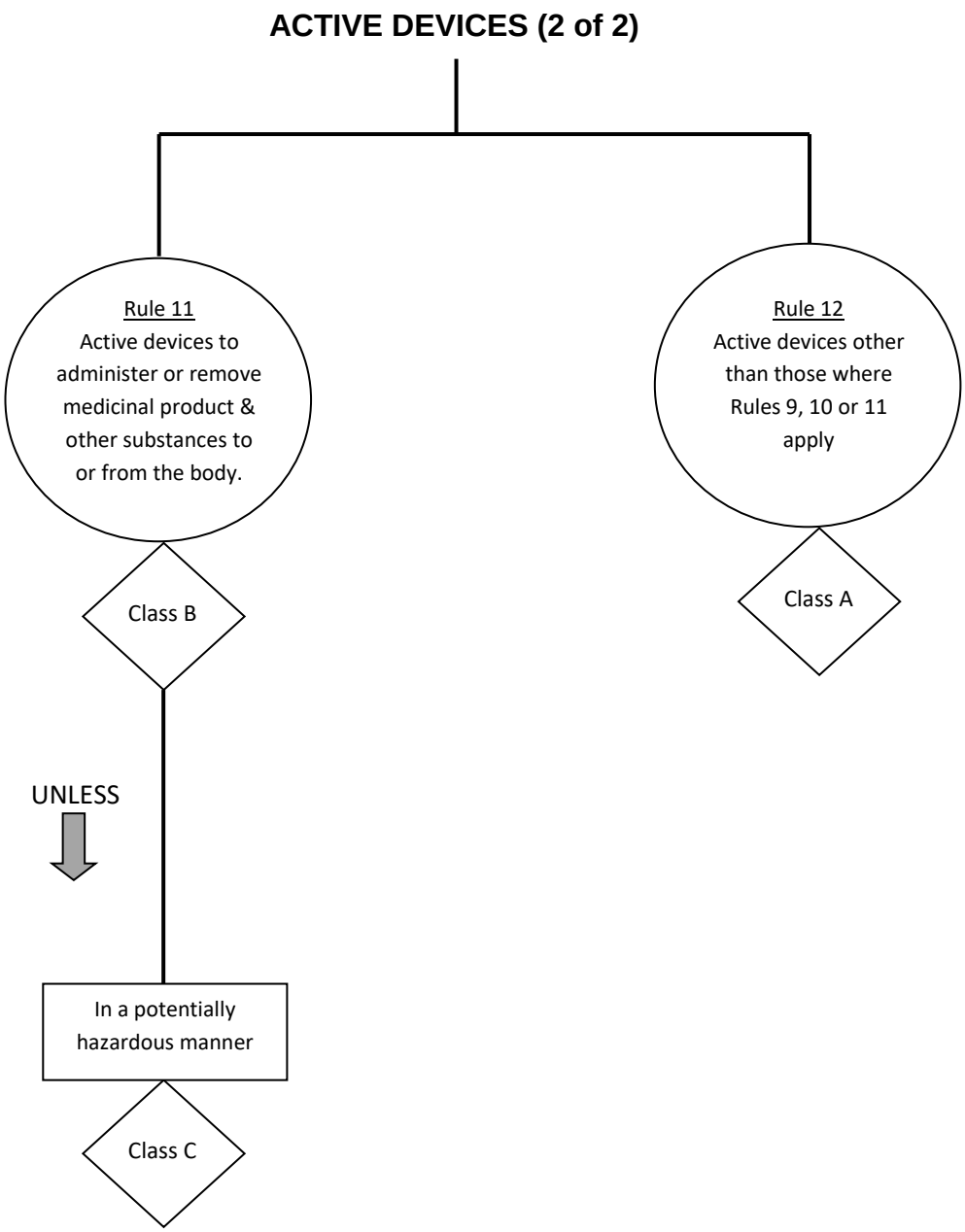

NON-INVASIVE DEVICES
Rule 1
Intended as a barrier, for compression or absorption of exudates only, for wounds that heal by primary intent
Class A
UNLESS
Intended to manage the microenvironment of the wound
Class B
UNLESS
For wounds that cannot heal by primary intent
Class C
Rule 2(i)
Channel tissues, channel or store body liquids, liquids or gases for eventual infusion or administration
Class A
UNLESS
Connected to an active medical device in Class B or higher
Class B
Rule 2(ii)
Channel blood, blood components, store organs, or parts of organs or tissues for eventual infusion or administration
Class B
UNLESS
Blood bags
Class C
Rule 3
Modify biological or chemical composition of blood/body liquids/other liquids intended
Class C
UNLESS
Action is filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
All other non-invasive devices that do not come into contact with the patient or contact intact skin only
Class A

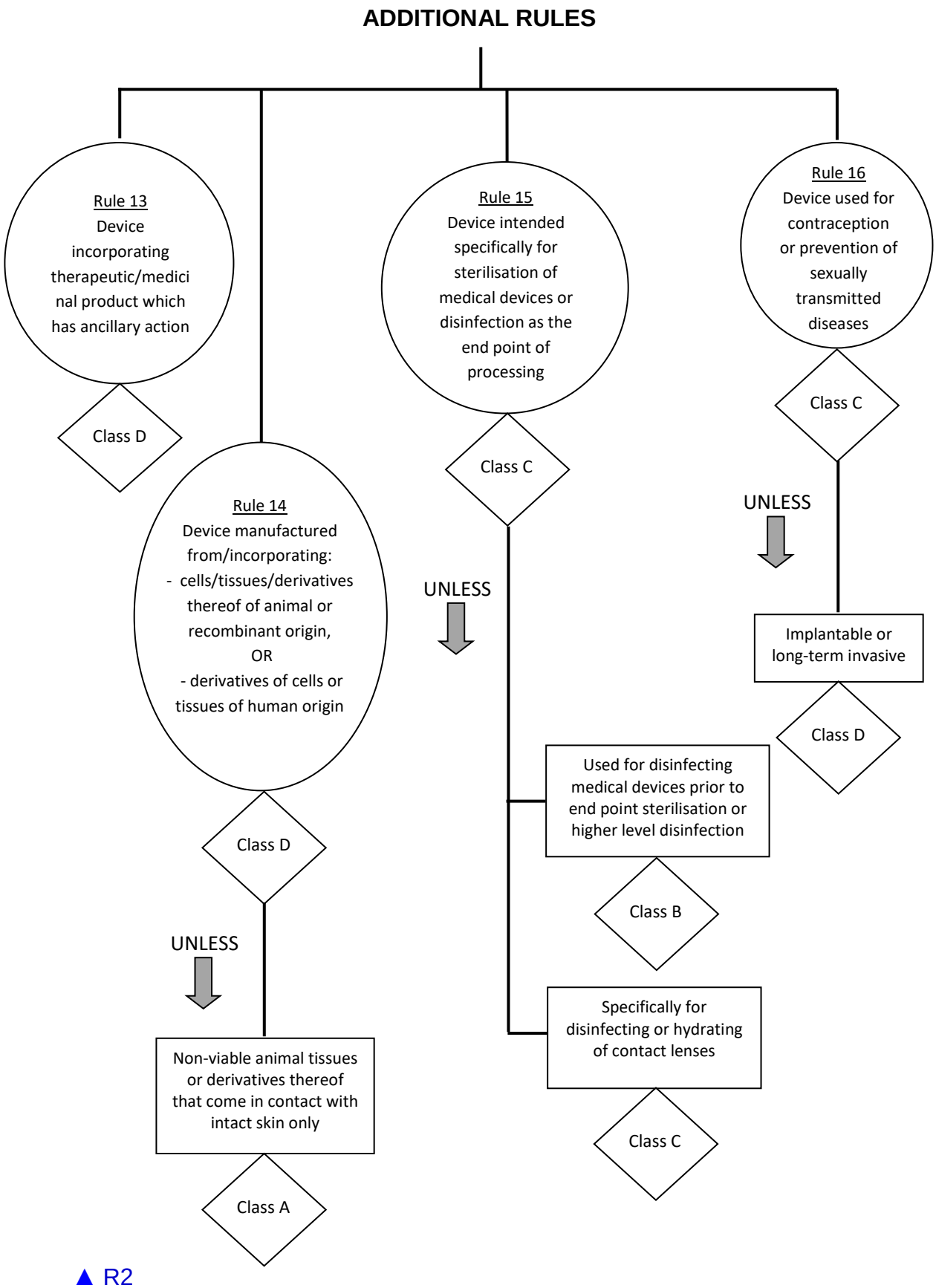

INVASIVE DEVICES (1 of 2)
Rule 5
Invasive through body orifice or stoma (not surgically invasive)
Rule 6
Surgically invasive - transient use (<60min)
UNLESS
Class B
Transient use
Class A
UNLESS
Used on eyeball & absorbed by mucous membrane
Class B
Short term use
Class B
UNLESS
Used in oral cavity, ear canal or nasal cavity only & not absorbed by mucous membrane
Class A
Long term use
Class C
UNLESS
Used in oral cavity, ear canal or nasal cavity only & not absorbed by mucous membrane.
Class B
If connected to an active medical device of Class B or higher
Class B
A reusable surgical instrument
Class A
Supplies ionising radiation
Class C
Biological effect or mainly absorbed
Class C
Administers medicinal products in a potentially hazardous manner
Class C
For use in direct contact with central nervous system
Class D
Intended to diagnose, monitor or correct a defect of heart or central circulatory system through direct contact
Class D

INVASIVE DEVICES (2 of 2)




ACTIVE DEVICES (1 of 2)
Rule 9(i)
Active therapeutic devices that are intended to administer/exchange energy or are software
Class B
UNLESS
Functions in a potentially hazardous way, including to administer/exchange energy (including ionising radiation)
Class C
Rule 9(ii)
Intended to control, monitor or directly influence the performance of active therapeutic devices in Class C or Class D
Class C
Rule 10(i)
Active diagnostic devices intended to allow direct diagnosis/monitoring of vital physiological processes, or supply energy that is absorbed, or intended to image in vivo radio-pharmaceuticals
Class B
UNLESS
The absorbed energy is for illumination only
Class A
The patient is, or could be, in immediate danger
Class C
Rule 10(ii)
Devices emitting ionising radiation and for diagnostic and/or interventional radiology devices, including their controls & monitors
Class C


ACTIVE DEVICES (2 of 2)
Rule 11
Active devices to administer or remove medicinal product & other substances to or from the body.
Class B
UNLESS
In a potentially hazardous manner
Class C
Rule 12
Active devices other than those where Rules 9, 10 or 11 apply
Class A


ADDITIONAL RULES
Rule 13
Device incorporating therapeutic/medicinal product which has ancillary action
Class D
Rule 14
Device manufactured from/incorporating:
- cells/tissues/derivatives thereof of animal or recombinant origin,
OR
- derivatives of cells or tissues of human origin
Class D
UNLESS
Non-viable animal tissues or derivatives thereof that come in contact with intact skin only
Class A
Rule 15
Device intended specifically for sterilisation of medical devices or disinfection as the end point of processing
Class C
UNLESS
Used for disinfecting medical devices prior to end point sterilisation or higher level disinfection
Class B
Specifically for disinfecting or hydrating of contact lenses
Class C
Rule 16
Device used for contraception or prevention of sexually transmitted diseases
Class C
UNLESS
Implantable or long-term invasive
Class D

▲ R2

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

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